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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,138

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Karl F. Johnson

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

MEAH, MOHAMMAD Y

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,138	Applicant(s) JOHNSON ET AL.	
	Examiner MD. YOUNUS MEAH	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/29/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/14/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

With preliminary amendment of this application, the applicant, on date 01/29/2008 elected with traverse Group II (claims 1-2, 4-5 and 7-8) drawn to method of production of fucosylated glycoprotein using fucosyltransferase comprising SEQ ID NO: 4, (claims 1-2, 4-5 and 7-8) for examination. Groups I and III-XVI (claims 3, 6, 9- 44) of election/restriction-office action of date 10/31/2007 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups.

Applicants argue that fucosyltransferase recited in US patent 6399337 (that used to break the common inventive concepts in election/restriction office action of 10/31/2007) has only 80% sequence identity to applicants SEQ ID NO: 4, therefore said art is not applicable and the claims are linked by a special technical feature.

This is not found persuasive because 90% sequence identity to SEQ ID NO:4 is not a shared technical feature as sequences having 90% identity to SEQ ID NOS: 2, 6 and 8 as recited in the non-elected groups comprise many polypeptides that do not have 90% identity to SEQ ID NO: 4. The only technical feature shared by all claims is fucosyl transferase activity and a polypeptide having fucosyl transferase activity is taught by US patent 6399337 thus this is not a special technical feature.

Therefore the restriction is maintained and made FINAL.

Claims 1-2, 4-5 and 7-8 will be examined.

Priority

Acknowledgement is made of applicant's PCT priority date based on application filing date of 07/23/2003 in GB # PCT/US03/23155 and US provisional application 60/398156, 7/23/02 and 60/424894, 11/08/02..

Information Disclosure Statement

The information disclosure statement received on the date 8/14/06 has been considered.

Objections

Claims 1-2 , 4-5 and 7-8 are objected to as reciting non-elected subject matter.

Claim Rejections

35 U.S.C 112

35 U.S.C 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 , 4-5, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2 , 4-5, are directed to method of making fucosylated glycoprotein by a reaction of any donor substrate having a fucose residue with any acceptor substrate on a glycoprotein in the presence of fucosyl transferase having at least 90% identity to SEQ ID NO: 4. The specification teaches only reactions of GDP fucose donor substrate reacting with few acceptor substrates which comprise a GlcNAc, . Like most of the Glycosyltransferase, fucosyltransferase is very specific transferase it needs specific donor such as GDP fucose to transfer fucose to specific acceptor such as GlcNAc moiety. Moreover the specification fails to describe any other species of acceptors and donor substrate by identifying their acceptor and donor capabilities. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-2 , 4-5 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of making fucosylated glycoprotein by a reaction of GDP fucose with a glycoprotein having GlcNAc residue of a glycoprotein using fucosyl transferase comprising SEQ ID NO: 4, does not reasonably provide enablement for method of making any fucosylated glycoprotein by a

reaction of any donor substrate having a fucose residue with any acceptor substrate on a glycoprotein in the presence of any polypeptide having 90% sequence identity to SEQ ID NO:4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims are 1-2 , 4-5 and 7-8 so broad as to encompass method of making any fucosylated glycoprotein by a reaction of any donor substrate having a fucose residue with any acceptor substrate on a glycoprotein in the presence of any polypeptide having 90% sequence identity to SEQ ID NO:4. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to extremely large number reactions involving extremely large number of donor substrates having a fucose residue with a extremely large number acceptor substrates on a glycoprotein in the presence of extremely large number fucosyl transferase polypeptides having 10% variation of SEQ ID NO: 4 broadly encompassed by the methods of the claims. The transferase activity of fucosyl transferase depends on the structure and nature of donor and acceptor molecule as well as structure of fucosyl transferase Like most of the Glycosyltransferase, fucosyltransferase is very specific transferase it needs specific donor such as GDP fucose to transfer fucose to specific acceptor such as GlcNAc moiety . Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the

ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only four fucosyl transferase polypeptides.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass methods method of making any fucosylated glycoprotein by a reaction of any donor substrate having a fucose residue with any acceptor substrate on a glycoprotein in the presence of any polypeptide having 90% sequence identity to SEQ ID NO:4. , because the specification does not establish: (A) regions of the protein structure which may be modified without effecting fucosyltransferase activity; (B) the general tolerance of fucosyltransferase activities to its modification and extent of such tolerance and functionality and structure of both donor and acceptor substrate; (C) a rational and predictable scheme for modifying donor, acceptor moiety and any fucosyltransferase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including method of making any fucosylated glycoprotein by a reaction of any donor substrate having a fucose residue with any acceptor substrate on a glycoprotein in the presence of any polypeptide having 90% sequence identity to SEQ ID NO:4,. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of fucosyltransferase for the use in the claimed methods having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

Claims 1-2 , 4-5 and 7-8 are rejected and no claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah, PhD
Examiner, Art Unit 1652
Recombinant Enzymes, 3C31 Remsen Bld
400 Dulany Street, Alexandria, VA 22314
Telephone: 517-272-1261

/Rebecca E. Prouty/
Primary Examiner,
Art Unit 1652